**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicant | : Gerardo Castillo *et al.* | Art Unit | : 1614 |
| Serial No. | : 09/748,748 | Examiner | : Zohreh Fay |
| Filed | : December 26, 2000 | Conf. No.: | 4503 |

Title : POLYHYDROXYLATED AROMATIC COMPOUNDS FOR THE TREATMENT OF AMYLODOSIS AND ALPHA-SYNUCLEIN FIBRIL DISEASES

**PETITION TO WITHDRAW FINALITY OF OFFICE ACTION**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby petition for the withdrawal of the finality of the Office Action mailed October 8, 2008. The withdrawal of the finality of the rejections of the above identified application is requested as the finality of the office action is premature under the terms of MPEP § 706.07(a). This petition invoking the supervisory authority of the Commissioner is brought under 37 C.F.R. § 1.181.

Under MPEP § 706, "[t]he goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity." The use of a new reference for the first time in a final office action undermines this goal and is improper under the terms of MPEP § 706.07(a), ¶2.

Claims 1-3, 17-26 and 29-30 have been rejected in the final Office action as allegedly anticipated by US patent no. US 5,733,926, being cited for the first time in the final Office Action.

The finality of this rejection is premature under MPEP § 706.07(a) because the Examiner has introduced "a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement … ." As discussed below, the rejection of claims 1-3, 17-26 and 29-30 over US patent no. US 5,733,926 after the previous Office action of March 21, 2008 was not necessitated by amendments of the claims and could have been raised at an earlier time.

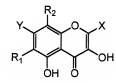
**Rejected claims**

In the response filed on June 17, 2008, applicant amended claims 1, 18, 24, 29 and 30 as follows:

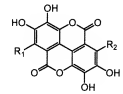
1. (Currently amended) A method of treating Alzheimer's disease, in a mammal suffering there from, comprising administration to the mammal of a therapeutically effective amount of an isolated pure compound selected from the group consisting of the compounds of formula A, formula B, formula C, and formula D~~, and formula E~~:


Formula A


Formula B




Formula C




Formula D

where:

$R_1$ and $R_2$ are independently selected from hydrogen and non-interfering substituents;

X is selected from hydrogen and the group consisting of

(a) hydroxy, amino, $C_{1-6}$ alkylamino, di($C_{1-6}$ alkyl)amino, and cycloamino,

(b) $C_{1-22}$ alkyl, $C_{1-22}$ alkoxy, $C_{1-22}$ alkylthio, and $C_{1-22}$ alkylcarboxyl, each optionally substituted

with 1 to 5 moieties selected from the group consisting of halogen, hydroxy, mercapto, amino, nitro, $C_{1-6}$ alkoxy, $C_{1-6}$ alkylthio, and $C_{1-6}$ alkylcarboxyl,

(c) aromatic and heteroaromatic groups substituted with ~~2 or~~ 3 adjacent hydroxy groups, and optionally substituted with 1 to 5 non-interfering substituents,

(d) sugars, optionally substituted with one or more anionic groups selected from sulfate, phosphate, phosphonate, carboxylate, and sulfonate groups, and

(e) peptides and peptide derivatives, and

Y is hydrogen, hydroxy, $C_{1-6}$ alkoxy, benzyloxy, where the phenyl group is optionally substituted with 1 to 3 substituents selected from halo and $C_{1-6}$ alkyl, or $-OSO_2R_4$, where $R_4$ is $C_{1-6}$ alkyl or phenyl optionally substituted with 1 to 3 substituents selected from halo and $C_{1-6}$ alkyl;

and the group of compounds consisting of acacetin, actinorhodine, alizarin, alizarin blue, alizarin orange, alizarinsulfonic acid, alkannin, anthragallol, anthralin, anthrarobin, antharufin, apigenin, apigetrin, apiose, baicalein, baptigenin, 1,2,4-benzenetriol, bostrycoidin, carbidopa, carminic acid, carubicin, cellobiose, centaurein, chloranilic acid, chondrosine, chromotrope 2B, chromotropic acid, chrysamminic acid, chrysarobin, chrysin, chrysophanic acid, cichoriin, citrazinic acid, citromycetin, collinomycin, curvularin, cyanidin, cyanidin 3-glucoside, cyanidin 3-rhamnoglucoside, cyanidin 3,5-diglucoside, cyanidin 3-sophoroside, daphnetin, datiscetin, daunorubicin, delphinidin, deoxyepinephrine, diosmetin, diosmin, dioxethedrine, dopa, dopamine, doxorubicin, droxidopa, echinochrome A, embelin, emodin, ergoflavin, eriodictyol, esculetin, fenoldopam, fomecin A, fomecin B, fraxetin, fraxin, fredericamycin A, fumigatin, fusarubin, fuscin, fustin, galangin, gallein, gallocyanine, gardenin A, gardenin B, gardenin C, gardenin D, gardenin E, genistein, gentisin, granaticin, guamecycline, hematein, hydroxysophorobioside, hydroxysophoricoside, icariin, isoquercitrin, ~~kaempferol,~~ kermesic acid, laccaic acid A, laccaic acid B, laccaic acid C, laccaic acid D, leucocyanidin, luteolin, maclurin, menogaril, methylenedigallic acid, morin, oosporein, phenicin, phloroglucide, puberulic acid, puberulonic acid, purpurin, purpurogallin, quercetagetin, quercimritrin, quinalizarin, quinic acid, resistomycin, rhamnetin, rhein, rhodizonic acid, rhodomycin A, rhodomycin B, robinin, ruberythric acid, rufigallol, rutin, scutellarein, tannic acid, tetroquinone, tiron, troxerutin, and tunichrome B1, but excluding pyrogallol,

and the pharmaceutically acceptable salts thereof.

18. (Currently amended) The method of Claim 1 where X is selected from hydrogen and the group consisting of

(a) hydroxy, amino, $C_{1-6}$ alkylamino, di($C_{1-6}$ alkyl)amino, and cycloamino,

(b) $C_{1-22}$ alkyl, $C_{1-22}$ alkoxy, $C_{1-22}$ alkylthio, and $C_{1-22}$ alkylcarboxyl, each optionally substituted with 1 to 5 moieties selected from the group consisting of halogen, hydroxy, mercapto, amino, nitro, $C_{1-6}$ alkoxy, $C_{1-6}$ alkylthio, and $C_{1-6}$ alkylcarboxyl, and

(c) aromatic and heteroaromatic groups substituted with ~~2 or~~ 3 adjacent hydroxy groups, and optionally substituted with 1 to 5 non-interfering substituents.

24. (Currently amended) The method of Claim 23 where the compound is ~~selected from the group consisting of~~ myricetin ~~and quercetin~~, and the pharmaceutically acceptable salts thereof.

29. (Currently amended) The method of Claim 1 where the active ingredient is selected from group of compounds consisting of acacetin, actinorhodine, alizarin, alizarin blue, alizarin orange, alizarinsulfonic acid, alkannin, anthragallol, anthralin, anthrarobin, antharufin, apigenin, apigetrin, apiose, baicalein, baptigenin, 1,2,4-benzenetriol, bostrycoidin, carbidopa, carminic acid, carubicin, cellobiose, centaurein, chloranilic acid, chondrosine, chromotrope 2B, chromotropic acid, chrysamminic acid, chrysarobin, chrysin, chrysophanic acid, cichoriin, citrazinic acid, citromycetin, collinomycin, curvularin, cyanidin, cyanidin 3-glucoside, cyanidin 3-rhamnoglucoside, cyanidin 3,5-diglucoside, cyanidin 3-sophoroside, daphnetin, datiscetin, daunorubicin, delphinidin, deoxyepinephrine, diosmetin, diosmin, dioxethedrine, dopa, dopamine, doxorubicin, droxidopa, echinochrome A, embelin, emodin, ergoflavin, eriodictyol, esculetin, fenoldopam, fomecin A, fomecin B, fraxetin, fraxin, fredericamycin A, fumigatin, fusarubin, fuscin, fustin, galangin, gallein, gallocyanine, gardenin A, gardenin B, gardenin C, gardenin D, gardenin E, genistein, gentisin, granaticin, guamecycline, hematein, hydroxysophorobioside, hydroxysophoricoside, icariin, isoquercitrin, ~~kaempferol,~~ kermesic acid, laccaic acid A, laccaic acid B, laccaic acid C, laccaic acid D, leucocyanidin, luteolin, maclurin, menogaril, methylenedigallic acid, morin, oosporein, phenicin, phloroglucide, puberulic acid, puberulonic acid, purpurin, purpurogallin, pyrocatechol, quercetagetin, quercimritrin, quinalizarin, quinic acid, resistomycin, rhamnetin, rhein, rhodizonic acid, rhodomycin A, rhodomycin B, robinin, ruberythric acid, rufigallol, rutin, scutellarein, tannic

acid, tetroquinone, tiron, troxerutin, and tunichrome B1, and the pharmaceutically acceptable salts thereof.

30. (Currently amended) The method of Claim 1 where the compound is selected from 1,2,4-benzenetriol, ellagic acid, 5-hydroxydopamine, myricetin, phloroglucide, ~~quercetin,~~ quinic acid, and tannic acid, and the pharmaceutically acceptable salts thereof.

Claims 2-3 and 17, 19-23 and 25-28 depend from claim 1 and ***were not amended*** in the response filed on June 17, 2008.

**Rejections in the final Office Action**

Claims 1-3, 17-26 and 29-30 are rejected as allegedly being anticipated over US Patent No. 5,733,926. The Examiner alleges that the reference teaches the use of genistein for the treatment of Alzheimer's disease.

To the extent that the claims are now properly rejected over the cited reference, they could have been so rejected in the previous Office Action. Therefore, the final Office Action introduces new grounds of rejection that are neither necessitated by applicants' amendment of the claims.

Accordingly, applicants respectfully request that the Examiner withdraw the finality of the Office action mailed on October 8, 2008 as premature pursuant to MPEP § 706.07(d) which states: "[i]f, on request by applicant for reconsideration, the primary examiner finds the final rejection to have been premature, he or she should withdraw the finality of the rejection." Therefore, withdrawal of the finality of these rejections is respectfully requested.

Please charge any fee which may be due for this submission of this petition to Jones Day Deposit Account No. 50-3013 (Order No. 712576-999002).

Respectfully submitted,

Date:January 6, 2009

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